

Medicaid Disability Manual

13.00 Malignant Neoplastic Diseases

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in 14.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus if you also have HIV infection.

B. *What do we consider when we evaluate malignant neoplastic diseases under these listings?* We consider factors such as the:

1. Origin of the malignancy.
2. Extent of involvement.
3. Duration, frequency, and response to antineoplastic therapy. Antineoplastic therapy means surgery, irradiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an antineoplastic treatment, we mean surgical excision for treatment, not for diagnostic purposes.
4. Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a malignancy originating from that specific site.

D. *What evidence do we need?*

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27.
2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:
 - a. Operative note.
 - b. Pathology report.
3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.
4. In some situations we may also need evidence about recurrence, persistence, or progression of the malignancy, the response to therapy, and any significant residuals. (See 13.00G.)

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E. When do we need longitudinal evidence?

1. ***Tumors with distant metastases.*** We generally do not need longitudinal evidence for tumors that have metastasized beyond the regional lymph nodes because these tumors usually meet the requirements of a listing. Exceptions are for tumors with distant metastases that are expected to respond to antineoplastic therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the intended effect of therapy has been achieved and is likely to persist.

2. ***Other malignancies.*** When there are no distant metastases, many of the listings require that we consider your response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities (multimodal) given in close proximity as a unified whole, and is usually planned before any treatment(s) is initiated. Examples of multimodal therapy include:

- a. Surgery followed by chemotherapy or radiation.
- b. Chemotherapy followed by surgery.
- c. Chemotherapy and concurrent radiation.

3. ***Types of treatment.*** Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure will often happen within 6 months after treatment starts, and there will often be a change in the treatment regimen. Whenever the initial planned therapy is multimodal, a determination about the effectiveness of the therapy usually cannot be made until the effects of all the planned modalities can be determined. In some cases, we may need to defer adjudication until the effectiveness of therapy can be assessed. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the malignancy or therapy (see 13.00G).

F. How do we evaluate impairments that do not meet one of the malignant neoplastic diseases listings?

1. These listings are only examples of malignant neoplastic diseases that we consider severe enough to prevent you from doing any gainful activity. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§404.1526 and 416.926.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial

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gainful activity. In that situation, we proceed to the fourth, and, if necessary, the fifth steps of the sequential evaluation process in §§404.1520 and 416.920. If you are an adult, we use the rules in §§404.1594 and 416.994, as appropriate, when we decide whether you continue to be disabled.

G. How do we consider the effects of therapy?

1. ***How we consider the effects of therapy under the listings.*** In many cases, malignancies meet listing criteria only if the therapy does not achieve the intended effect: the malignancy persists, progresses, or recurs despite treatment. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. Effects can vary widely.

a. Because the therapy and its toxicity may vary widely, we consider each case on an individual basis. We will request a specific description of the therapy, including these items:

- i. Drugs given.
- ii. Dosage.
- iii. Frequency of drug administration.
- iv. Plans for continued drug administration.
- v. Extent of surgery.
- vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

- i. Continuing gastrointestinal symptoms.
- ii. Persistent weakness.
- iii. Neurological complications.
- iv. Cardiovascular complications.
- v. Reactive mental disorders.

3. ***Effects of therapy may change.*** Because the severity of the adverse effects of antineoplastic therapy may change during treatment, enough time must pass to allow us

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to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances. But, on occasion, the effects may be disabling for a consecutive period of at least 12 months.

4. ***When the initial antineoplastic therapy is effective.*** We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet or medically equal a listing, we must consider its affect on your ability to do substantial gainful activity.

H. How long do we consider your impairment to be disabling?

1. In some listings, we specify that we will consider your impairment to be disabling until a particular point in time (for example, at least 18 months from the date of diagnosis). We may consider your impairment to be disabling beyond this point the medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling until at least 3 years after onset of complete remission. When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or medically equal the criteria of a listing in this body system.

3. Following the appropriate period, we will consider any residuals, including residuals of the malignancy or therapy (see 13.00G), in determining whether you are disabled.

I. What do these terms in the listings mean?

1. ***Inoperable:*** Surgery is thought to be of no therapeutic value or the surgery cannot be performed. Examples of when surgery cannot be performed include a tumor that is too large or that invades crucial structures, or an intolerance of anesthesia or surgery due to other medical conditions. This term does not include situations in which the tumor could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. The determination whether a tumor is inoperable usually occurs before attempts to shrink the tumor with chemotherapy or radiation.

2. ***Unresectable:*** The operation was performed, but the malignant tumor was not removed. This term includes situations in which a tumor is incompletely resected or the surgical margins are positive.

3. ***Persistent:*** Failure to achieve a complete remission.

4. ***Progressive:*** The malignancy became more extensive after treatment.

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5. ***Recurrent, relapse:*** A malignancy that had been in complete remission or entirely removed by surgery has returned.

J. ***Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the malignancy satisfies the criteria of a listing?*** Yes. We will consider factors such as:

1. The type of malignancy and its location.
2. The extent of involvement when the malignancy was first demonstrated.
3. Your symptoms.

K. How do we evaluate specific malignant neoplastic diseases?

1. ***Lymphoma.***

a. Many low grade or indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although they may produce intermittent symptoms and signs. Therefore, we may defer adjudication of these cases for an appropriate period after initiation of therapy to determine whether the therapy will achieve its intended effect. (See 13.00E3.) For a low grade or indolent lymphoma, the intended effect of therapy is usually stability of the disease process. When stability has been achieved, we will assess severity on the basis of the extent of involvement of other organ systems and residuals from therapy.

b. A change in therapy for low grade or indolent lymphoma is usually an indicator that the therapy is not achieving its intended effect. However, it does not indicate this if the change is based on your (or your physician's) choice rather than a failure to achieve stability. If the therapy is changed due solely to choice, the requirements of listing 13.05A2a are not met.

c. We consider Hodgkin's disease that recurs more than 12 months after completing initial antineoplastic therapy to be a new disease rather than a recurrence.

2. ***Leukemia.***

a. ***Acute leukemia.*** The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based upon definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. The initial and follow-up pathology reports should be included.

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b. ***Chronic myelogenous leukemia (CML)***. The diagnosis of CML should be based upon documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice.

c. ***Chronic lymphocytic leukemia.***

i. The diagnosis of chronic lymphocytic leukemia (CLL) must be documented by evidence of a chronic lymphocytosis of at least 10,000/mm³ for 3 months or longer, or other acceptable diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

ii. We evaluate the complications and residual impairment(s) from CLL under the appropriate listings, such as 13.05A2, 7.02, and 7.15.

d. ***Elevated white cell count.*** In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not ordinarily a factor in determining the severity of the impairment.

3. ***Macroglobulinemia or heavy chain disease.*** The diagnosis of these diseases must be confirmed by protein electrophoresis or immunoelectrophoresis. We evaluate the resulting impairment(s) under the criteria of 7.02, 7.06, 7.08, or any other affected body system.

4. ***Bilateral primary breast cancer.*** We evaluate bilateral primary breast cancer (synchronous or metachronous) under 13.10A, which covers local primary disease, and not as a primary disease that has metastasized.

5. ***Carcinoma-in-situ.*** Carcinoma-in-situ, or preinvasive carcinoma, usually responds to treatment. When we use the term "carcinoma" in these listings, it does not include carcinoma-in-situ.

6. ***Brain tumors.*** We use the criteria in 13.13 to evaluate malignant brain tumors. We will evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 11.05.

L. ***How do we evaluate malignant neoplastic diseases treated by bone marrow or stem cell transplantation?*** Bone marrow or stem cell transplantation is performed for a variety of malignant neoplastic diseases.

1. ***Acute leukemia (including T-cell lymphoblastic lymphoma) or accelerated or blast phase of CML.*** If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of

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diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. ***Lymphoma, multiple myeloma, or chronic phase of CML.*** If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. ***Other malignancies.*** We will evaluate any other malignant neoplastic disease treated with bone marrow or stem cell transplantation under 13.28, regardless of whether there is another listing that addresses that impairment. The length of time we will consider you to be disabled depends on whether you undergo allogeneic or autologous transplantation.

a. ***Allogeneic bone marrow or stem cell transplantation.*** If you undergo allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin), we will consider you to be disabled until at least 12 months from the date of transplantation.

b. ***Autologous bone marrow or stem cell transplantation.*** If you undergo autologous transplantation (transplantation of your own cells or cells from your identical twin (syngeneic transplantation)), we will consider you to be disabled until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. The first treatment usually refers to the initial therapy given to prepare you for transplantation.

4. ***Evaluating disability after the appropriate time period has elapsed.*** We consider any residual impairment(s), such as complications arising from:

- a. Graft-versus-host (GVH) disease.
- b. Immunosuppressant therapy, such as frequent infections.
- c. Significant deterioration of other organ systems.

13.01 Category of Impairments, Malignant Neoplastic Diseases

13.02 *Soft tissue tumors of the head and neck (except salivary glands—13.06—and thyroid gland – 13.07).*

A. Inoperable or unresectable.

OR

B. Persistent disease following initial multimodal antineoplastic therapy.

OR

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C. Recurrent disease following initial antineoplastic therapy, except local vocal cord recurrence.

OR

D. With metastases beyond the regional lymph nodes.

OR

E. Soft tissue tumors of the head and neck not addressed in A-D, with multimodal antineoplastic therapy. Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.03 Skin.

A. Sarcoma or carcinoma with metastases to or beyond the regional lymph nodes.

OR

B. Melanoma, with either 1 or 2:

1. Recurrent after wide excision (except an additional primary melanoma at a different site, which is not considered to be recurrent disease).
2. Palpable nodal metastases or metastases to adjacent skin (satellite lesions) or elsewhere.

13.04 Soft tissue sarcoma.

A. With regional or distant metastases.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

13.05 Lymphoma (including mycosis fungoides, but excluding T-cell lymphoblastic lymphoma-13.06). (See 13.00K1 and 13.00K2c.)

A. Non-Hodgkin's lymphoma, as described in 1 or 2:

1. Intermediate or high-grade lymphoma persistent or recurrent following initial antineoplastic therapy.

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2. Low-grade or indolent lymphoma requiring initiation of more than one antineoplastic treatment regimen within a consecutive 12-month period. Consider under a disability from at least the date of initiation of the treatment regimen that failed within 12 months.

OR

B. Hodgkin's disease with failure to achieve clinically complete remission, or recurrent disease within 12 months of completing initial antineoplastic therapy.

OR

C. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.06 Leukemia. (See 13.00K2.)

A. Acute leukemia (including T-cell lymphoblastic lymphoma). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Chronic myelogenous leukemia, as described in 1 or 2:

1. Accelerated or blast phase. Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

2. Chronic phase, as described in a or b:

a. Consider under a disability until at least 12 months from the date of bone marrow or stem cell transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

b. Progressive disease following initial antineoplastic therapy.

13.07 Multiple myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings).

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A. Failure to respond or progressive disease following initial antineoplastic therapy.

OR

B. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.08 Salivary glands - carcinoma or sarcoma with metastases beyond the regional lymph nodes.

13.09 Thyroid Gland.

A. Anaplastic (undifferentiated) carcinoma.

OR

B. Carcinoma with metastases beyond the regional lymph nodes progressive despite radioactive iodine therapy.

13.10 Breast (except sarcoma—13.04) (See 13.00K4.)

A. Locally advanced carcinoma (inflammatory carcinoma, tumor of any size with direct extension to the chest wall or skin, tumor of any size with metastases to the ipsilateral internal mammary nodes.

B. Carcinoma with distant metastases.

OR

C. Recurrent carcinoma, except local recurrence that remits with antineoplastic therapy.

13. 11 Skeletal system -- carcinoma or sarcoma.

A. Inoperable or unresectable.

OR

B. Recurrent tumor (except local recurrence) after initial antineoplastic therapy.

OR

C. With distant metastases.

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OR

D. All other tumors originating in bone with multimodal antineoplastic therapy. Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.12 *Maxilla, orbit, or temporal fossa.*

A. Sarcoma or carcinoma of any type with regional or distant metastases.

OR

B. Carcinoma of the antrum with extension into the orbit or ethmoid or sphenoid sinus.

OR

C. Tumors with extension to the base of the skull, orbit, meninges, or sinuses.

13.13 *Nervous system.* (See 13.00K6.)

A. Central nervous system neoplasms (brain and spinal cord), as described in 1 or 2:

1. Highly malignant tumors, such as Grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, diffuse intrinsic brain stem gliomas, or primary sarcomas.

2. Any central nervous system neoplasm progressive or recurrent following initial antineoplastic therapy.

OR

B. Peripheral nerve or spinal root neoplasm, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

13.14 *Lungs.*

A. Non-small-cell carcinoma--inoperable, unresectable, recurrent, or metastatic disease to or beyond the hilar nodes.

OR

B. Small-cell (oat cell) carcinoma.

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13.15 *Pleura or Mediastinum.*

A. Malignant mesothelioma of pleura.

OR

B. Tumors of the mediastinum, as described in 1 or 2:

1. With metastases to or beyond the regional lymph nodes.
2. Persistent or recurrent following initial antineoplastic therapy.

13.16 *Esophagus or stomach.*

A. Carcinoma or sarcoma of the esophagus.

OR

B. Carcinoma or sarcoma of the stomach, as described in 1 or 2:

1. Inoperable, unresectable, extending to surrounding structures, or recurrent.
2. With metastases to or beyond the regional lymph nodes.

13.17 *Small intestine* --carcinoma, sarcoma, or carcinoid.

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases beyond the regional lymph nodes.

13.18 *Large intestine (from ileocecal valve to and including anal canal).*

A. Adenocarcinoma that is inoperable, unresectable, or recurrent.

OR

B. Squamous cell carcinoma of the anus, recurrent after surgery.

OR

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C. With metastases beyond the regional lymph nodes.

13.19 *Liver or Gallbladder* -- tumors of the liver, gallbladder, or bile ducts.

13.20 *Pancreas*.

A. Carcinoma (except islet cell carcinoma).

OR

B. Islet cell carcinoma that is inoperable or unresectable and physiologically active.

13.21 *Kidneys, adrenal glands, or ureters* - carcinoma.

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases to or beyond the regional lymph nodes.

13.22 *Urinary bladder* - carcinoma.

A. With infiltration beyond the bladder wall.

OR

B. Recurrent after total cystectomy.

OR

C. Inoperable or unresectable.

OR

D. With metastases to or beyond the regional lymph nodes.

13.23 *Cancers of the female genital tract* - carcinoma or sarcoma.

A. Uterus (corpus), as described in 1, 2, or 3:

1. Invading adjoining organs.

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2. With metastases to or beyond the regional lymph nodes.
3. Persistent or recurrent following initial antineoplastic therapy.

OR

B. Uterine cervix, as described in 1 or 2:

1. Extending to the pelvic wall, lower portion of the vagina, or adjacent or distant organs.
2. Persistent or recurrent following initial antineoplastic therapy.

OR

C. Vulva, as described in 1, 2, or 3:

1. Invading adjoining organs.
2. With metastases to or beyond the regional lymph nodes.
3. Persistent or recurrent following initial antineoplastic therapy.

OR

D. Fallopian tubes, as described in 1 or 2:

1. Extending to the serosa or beyond.
2. Persistent or recurrent following initial antineoplastic therapy.

OR

E. Ovaries, as described in 1 or 2:

1. All tumors except germ-cell tumors, with at least one of the following:
 - a. Tumor extension beyond the pelvis; for example, tumor implants on peritoneal, omental, or bowel surfaces.
 - b. Metastases to or beyond the regional lymph nodes.
 - c. Ruptured ovarian capsule, tumor on the serosal surface of the ovary, ascites with malignant cells, or positive peritoneal washings.
 - d. Recurrent following initial antineoplastic therapy.

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2. Germ-cell tumors--progressive or recurrent following initial antineoplastic therapy.

13.24 *Prostate gland* - carcinoma.

A. Progressive or recurrent despite initial hormonal intervention.

OR

B. With visceral metastases.

13.25 *Testicles* - tumor with metastatic disease progressive or recurrent following initial chemotherapy.

13.26 *Penis* - carcinoma with metastases to or beyond the regional lymph nodes.

13.27 *Primary site unknown after appropriate search for primary* - metastatic carcinoma or sarcoma, except for solitary squamous cell carcinoma in the neck.

13.28 *Malignant neoplastic diseases treated by bone marrow or stem cell transplantation.* (See 13.00L.)

A. Allogeneic transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Autologous transplantation. Consider under a disability until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.